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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,345	06/23/2003	Andres F. Zuluaga	12258-029001	1603

26161 7590 10/13/2006

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EXAMINER

SOLANKI, PARIKHA

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,345	ZULUAGA ET AL.	
	Examiner	Art Unit	
	Parikha Solanki	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003 and 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 14-19, 22-42, 45 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 20, 21, 43, 44 and 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/03, 11/24/04, 3/1/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 2-13, 20, 21, 43, 44 and 46-51 in the reply filed on 7 September 2006 is acknowledged. Examiner also acknowledges that Applicant made a typographical error in omitting claim 1 from the group of elected claims listed in the reply, as is detailed in form PTO-413 submitted with this office action, and as such claim 1 will also be considered for further examination.
2. Claims 14-19, 22-42, 45, and 52-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species of the present invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 September 2006.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-13, 20, 21, 43, 44 and 46-51 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 10, 11, 15, 17 and 18 of copending Application No. 10/940468. Examiner contends that the atraumatic coupler of the invention of the instant application is inherently divergence-limiting, as claimed by the conflicting co-pending application, and as such both applications claim the same invention. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-

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type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-13, 20, 21, 43, 44 and 46-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 15, 17 and 18 of copending Application No. 10/940468. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specific claims of the co-pending application anticipate the broad claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 38 (Figure 3).

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

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notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the features of claims 7-9, 43 and 44 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. The abstract of the disclosure is objected to because there is a typographical error in line 2. It is suggested that the phrase "an coupler" should be replaced by "a coupler". Appropriate correction is required. See MPEP § 608.01(b).

Claim Objections

10. Claim 6 is objected to because of the following informalities: there is a typographical error in line 1. It is recommended that the letter "e" following the word "apparatus" be removed. Appropriate correction is required.

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11. Claim 51 is objected to because of the following informalities: there is insufficient antecedent basis for the phrase "The apparatus of claim 43" in line 1. It appears that applicant intended for claim 51 to depend from claim 46. For the purposes of examination, claim 51 has been treated as though it depends from claim 46. Appropriate correction is required.

12. Claims 8 and 9 are objected to because of the following informalities: the bow, arc and catenary curve shapes described by these claims appear to be identical, and no supporting illustration or description is provided in the specification so as to show otherwise. It is suggested that figures depicting the probe assuming arc and catenary curve shapes, and further depicting the differences between arc, catenary curve and bow shapes should be included in the drawings section, and that the appropriate corresponding descriptions be added to the specification. For the purposes of examination, Examiner will assume that a bow, arc and catenary curve are identical shapes for the remainder of this office action.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

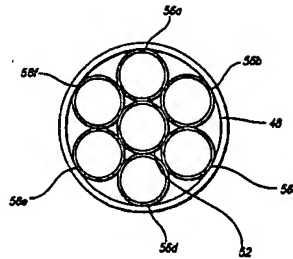
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1, 2, 5, 10, 11, 20, 21, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Moreno ('137). Regarding claim 1, Moreno ('137) discloses a fiber-optic probe connected to a light source, including a light directing or focusing mechanism (abstract line 1). Moreno ('137) discloses this invention for the specific purpose of non-destructively detecting vulnerable plaques in living tissue (§ 0011).

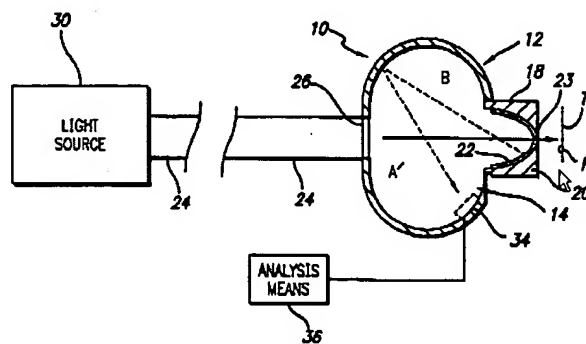
Regarding claim 2, Moreno ('137) shows a jacket encasing the optical fiber(s) (Figure 15).



(Source: Moreno et al, US Pub No. 2001/0047137)

Regarding claim 5, Moreno ('137) discloses a fiber-optic probe comprising multiple optical fibers (§ 0013).

Regarding claims 10-11, Moreno ('137) discloses an atraumatic coupler comprising a lens mounted on the distal end of the fiber-optic probe (Figure 1).



(Source: Moreno et al, US Pub No. 2001/0047137)

Regarding claim 20, Moreno ('137) discloses a near-infrared light source for illuminating the probe (abstract, line 3).

Regarding claim 21, Moreno ('137) discloses a computer system in communication with the probe, the computer being configured to analyze the light reflected by the tissue in contact with the distal end of the probe as an indicator of plaque presence (§ 0013).

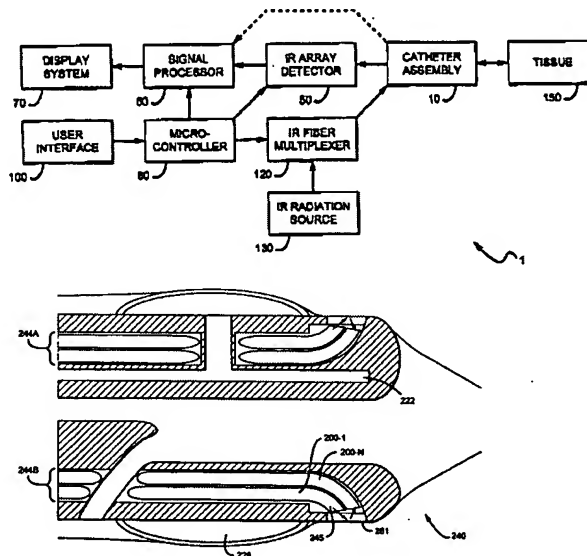
Regarding claims 43 and 44, Moreno ('137) discloses a method for detecting vulnerable plaque comprising the steps of focusing light on tissue and receiving light reflected by the tissue via an apparatus that has an atraumatic coupler at its distal end, which may be placed in contact with the intraluminal wall, and equipment for analyzing

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the spectra of the reflected light to indicate presence or absence of a vulnerable plaque (¶ 0012). The method of Moreno ('137) employs a distally located atraumatic light coupler which is capable of contacting the intraluminal wall.

15. Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by Casscells ('071).

Regarding claim 46, Casscells ('071) discloses a probe having an optical fiber extending therethrough, a means for atraumatically contacting and optically communicating with the intraluminal wall, a light source in optical communication with the fiber for illumination, and a detector in optical communication with the fiber (Figs 1 & 20c).



(Source: Casscells ('071), Figures 1 & 20c)

Claim Rejections - 35 USC § 103

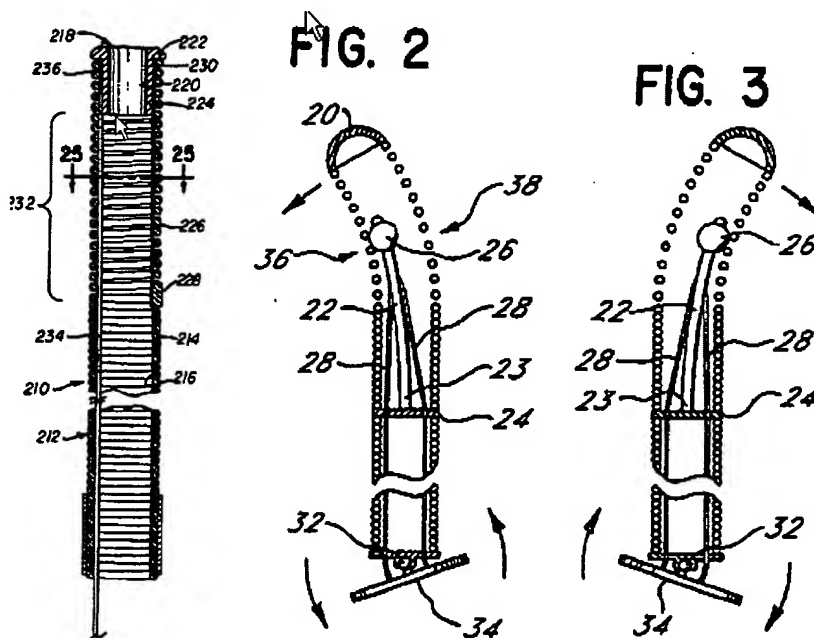
16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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17. Claims 3 and 6-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno ('173) in view of Hammerslag ('587).

Regarding claim 3, Moreno ('173) discloses an apparatus meeting all limitations of claims 1 and 2 as described above. Moreno is silent with respect to the structure of the jacket, but does not teach away from it being comprised of a wound coil-wire. Hammerslag ('587) teaches the use of a coiled wire sheath in conjunction with catheters, cannulae, guidewires and the like for the purpose of enhancing steerability of such medical devices (col 1 line 14, Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Hammerslag ('587) and Moreno ('173) to enhance the steerability of a fiber optic catheter assembly by encasing it in a coil-wire wound jacket.



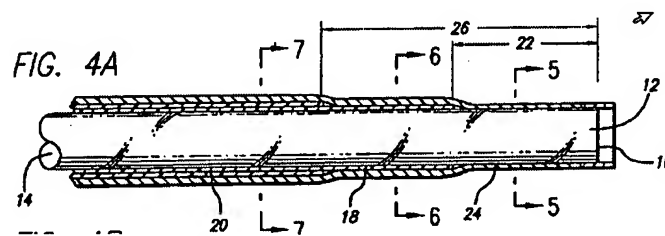
(Source: Hammerslag ('587) Figures 1-3)

Regarding claims 6-9, Moreno ('173) discloses all limitations of claim 1 as described above. Hammerslag ('587) teaches the use of a coiled wire sheath in conjunction with catheters, cannulae, guidewires and the like for the purpose of enhancing steerability of such medical devices, which further includes at least one pull wire to effect lateral deflection of the device tip (Figs 2 and 3), so as to aid in guiding such a device through tortuous vasculature. Such a deflection mechanism is inherently capable of resiliently deforming a catheter to assume a bow, catenary or arc shape. Therefore, it would have been obvious to one of ordinary skill at the time of invention to

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modify the probe of Moreno ('173) such that it would be capable of assuming a resilient bow, arc or catenary shape to allow for navigating tortuous vasculature, in view of the teachings of Hammerslag ('587).

18. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno ('173) in view of Hammerslag ('587) as applied to claim 3 above, and further in view of Derbin ('021). Derbin ('021) teaches the use of a variable-thickness catheter shaft in order to provide variations in stiffness along the length of the catheter, more specifically to make the distal tip more flexible than the rest of the body (Fig 4A).



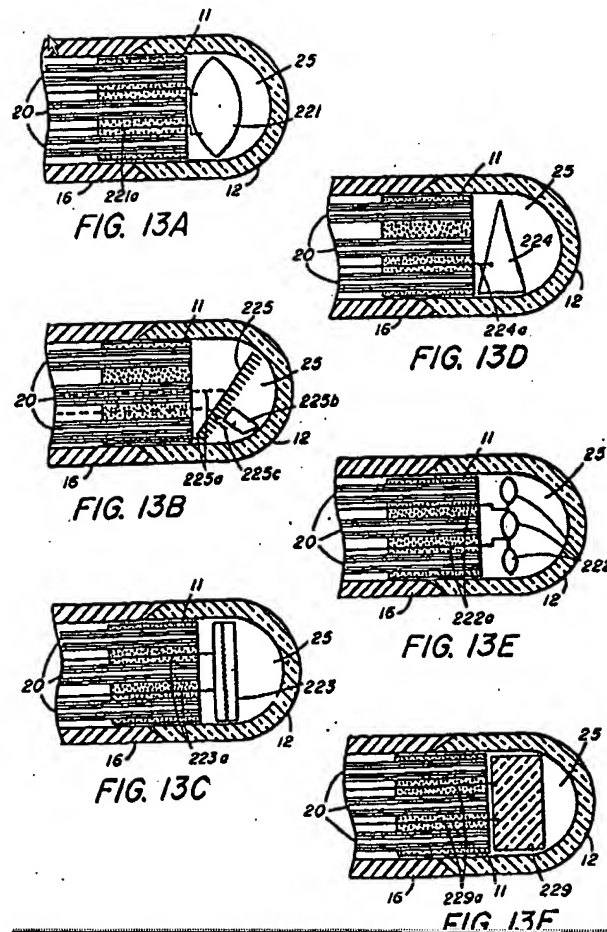
(Source: Derbin ('021) Figure 4a)

Furthermore, Moreno ('173) and Hammerslag ('587) do not teach away from varying the thickness of the catheter jacket. As such, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Moreno ('173), previously modified in view of Hammerslag ('587), to further include a variable-diameter coil-wound jacket so as to provide for distal flexibility while also providing for proximal stiffness, in view of the teachings of Derbin ('021).

19. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno ('173) in view of Utzinger (2003). Moreno ('173) discloses all limitations of claim 1 as described above. Moreno ('173) does not specify whether the coupler may be integral with the optical fiber. Utzinger (2003) teaches that cleaving and polishing the end of an optical fiber to create a beveled or flat end surface creates a coupling surface that is more efficient than a lens coupler (p. 123 ¶ 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Moreno ('173) to integrate the coupler with the distal tip of its optical fiber in order to enhance the coupling efficiency, in view of the teachings of Utzinger (2003).

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20. Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells ('071) in view of Kittrell ('010). Casscells ('071) discloses all limitations of claim 46 as described above. Casscells ('071) does not disclose a rounded distal tip or contacting the intraluminal wall. Kittrell ('010) discloses a rounded distal tip, and further discloses a lens and diffraction grating to be used at the point of illumination to better control the direction of the illuminating light (Figs 13A & 13B). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Casscells ('071) to further include a rounded surface that may also include a lens or diffraction grating to better control the direction of the illuminating light emitted by the probe assembly, in view of the teachings of Kittrell ('010).



(Source: Kittrell ('010) Figure 13)

21. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells ('071) in view of Kittrell ('010), and further in view of Utzinger (2003). Casscells ('071) and Kittrell ('010) disclose the limitations of claims 46 and 47 as

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described above, but do not disclose a rounded tip of the distal fiber to be used for direct atraumatic contact with the intraluminal wall. Utzinger (2003) discloses that the end of an optical fiber may be cleaved, polished and beveled in order to provide a more efficient coupling surface that will maintain a small probe diameter (p 121 & 123). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Cascells ('071), previously modified in view of Kittrell ('010), to further include an optical fiber with a rounded distal surface so as to increase the coupling efficiency while maintaining a small probe diameter, in view of the teachings of Utzinger (2003).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha Solanki
Examiner – Art Unit 3737


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